Mepolizumab and Omalizumab Benefits to Change for Texas Medicaid on November 1, 2016

Effective for dates of service on or after November 1, 2016, mepolizumab and omalizumab benefits will change for Texas Medicaid. Major changes to this medical benefit policy include the following:

- Procedure code C9473, mepolizumab, will be a benefit for Texas Medicaid clients if medical necessity criteria are met with submission of documentation. Prior authorization will be required.
- Prior authorization for an initial request for mepolizumab will be considered when the client has had an inadequate response after being compliant for six months of treatment with omalizumab (procedure code J2357) and the client meets all the criteria for mepolizumab. Exceptions may be considered with supporting documentation.
- Omalizumab and mepolizumab may not be used concurrently. Procedure code C9473 will be denied when submitted on the same date of service as procedure code J2357, by any provider.

Prior Authorization Portal Changes in Fee-For-Service

The checkbox currently titled "Omalizumab" on the prior authorization portal screen on the TMHP website will be renamed “Monoclonal Antibodies - Asthma & Chronic Idiopathic Urticaria". Providers must use this checkbox when requesting prior authorization for omalizumab or mepolizumab.

Note: *Prior authorization requests submitted by fax or mail for omalizumab or mepolizumab must still be submitted using the Special Medical Prior Authorization (SMPA) Request Form.*

Omalizumab

Omalizumab is FDA approved for the treatment of clients who are 6 and older with moderate to severe asthma (as defined by the National Heart, Lung, and Blood Institute’s Guidelines for the Diagnosis and Management of Asthma). Omalizumab is also approved for the treatment of clients who are 12 years of age and older with chronic idiopathic urticaria, who remain symptomatic despite H1 antihistamine treatment. Clients who are younger than the FDA-approved age will be considered on a case-by-case basis by the TMHP medical director.

Providers may not bill for an office visit if the only reason for the visit is an omalizumab injection.

Additional Documentation for Omalizumab

The following additional documentation for treatment with omalizumab also must be submitted:

- Positive skin test or radioabsorbent assay test (RAST) to a perennial (not seasonal) aeroallergen within the past 36 months.
- Total IgE level greater than 30 IU/ml but less than 700 IU/ml within the past 12 months

Mepolizumab

Mepolizumab is an injectable drug that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of clients who are 12 and older and have severe asthma (as defined by the National Heart, Lung, and Blood Institute’s Guidelines for the Diagnosis and Management of Asthma) with an eosinophilic phenotype. Clients who are younger than the FDA-approved age will be considered on a case-by-case basis by the TMHP medical director.

Mepolizumab procedure code C9473 will be a benefit when prior authorized and provided by the following:

- Nurse practitioner, clinical nurse specialist, physician assistant, and physician providers in the office setting
- Hospital providers in the outpatient hospital setting

Providers may not bill for an office visit if the only reason for the visit is a mepolizumab injection.

Treatment with mepolizumab may not occur concurrently with omalizumab or any other interleukin-5 antagonist. Procedure code C9473 will be denied when submitted on the same date of service as procedure code J2357, by any provider.

TMHP prior authorizations for mepolizumab will be for intervals of six months at a time. Clients must be compliant with their mepolizumab regimen in order to qualify for additional authorizations. The provider must submit a statement documenting compliance with the requests for each renewal.

Additional Documentation for Mepolizumab

The following additional documentation for treatment with mepolizumab must also be submitted:

- One of the following blood eosinophil counts in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection:
    - Greater than or equal to 150 cells/microliter at initiation of therapy; OR
    - Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

Note: *1 microliter (ul) is equal to 1 cubic millimeter (mm3)*

- Prior authorization for an initial request for mepolizumab will be considered at TMHP when the client has had an inadequate response after being compliant for 6 months of treatment with omalizumab and meets the criteria for mepolizumab. Failure to respond to omalizumab must be documented in a letter, signed and dated by the prescribing provider and submitted with the request.

Note: *Exceptions may be considered for clients who meet the criteria for treatment with mepolizumab but do not meet the criteria for omalizumab. Supporting documentation, such as an IgE level that falls outside of the required range or a negative skin test/RAST to a perennial aeroallergen, must be submitted along with the documentation for treatment with mepolizumab, as described above.*

Prior Authorization Criteria for Chronic Idiopathic Urticaria in Fee-For-Service

Prior authorization for omalizumab will be considered at TMHP for clients who are 12 years of age or older with chronic idiopathic urticaria (CIU). Documentation supporting medical necessity for treatment of CIU with omalizumab must be submitted with the request and include all of the following:

- Documented failure of, or contraindication to, antihistamine and leukotriene inhibitor therapies.
- Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.

When requesting prior authorization, the exact dosage must be included with the request.

Prior Authorization Criteria for Asthma: Moderate to Severe (Omalizumab) and Severe (Mepolizumab) in Fee-For-Service

Requests for prior authorization must be submitted by the treating physician to TMHP's Special Medical Prior Authorization (SMPA) department by mail or approved electronic method using the SMPA request form.

Documentation supporting medical necessity for treatment of asthma with omalizumab or mepolizumab must be submitted with the request and must indicate the following:

- Symptoms are inadequately controlled with use of one of the following combination therapies:
    - 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; or
    - 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents.

Note: *Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for omalizumab or mepolizumab, the client's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by the TMHP medical director.*

- Pulmonary function tests must have been performed within a three-month period and be documented for all clients.

Note: *Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.*

- Client is not currently smoking.
- When requesting prior authorization, the exact dosage must be included with the request.

Requirements for Continuation of Therapy

For continuation of therapy with omalizumab or mepolizumab after 6 continuous months, the requesting provider must submit the following documentation of the client's compliance and satisfactory clinical response to omalizumab or mepolizumab:

- Documentation of clinical improvement must include one or more of the following:
    - Decreased utilization of rescue medications; OR
    - Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline; OR
    - Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
        - Asthma attacks
        - Chest tightness or heaviness
        - Coughing or clearing throat
        - Difficulty taking deep breath or difficulty breathing out
        - Shortness of breath
        - Sleep disturbance, night wakening, or symptoms upon awakening
        - Tiredness
        - Wheezing/heavy breathing/fighting for air, AND
- Member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab or mepolizumab.

After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by the TMHP medical director.

Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the TMHP medical director.